

# Exhibit H



June 20, 2019

Norman Sharpless, M.D.  
Acting Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue NW  
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write to convey the organization's support for removing the current Risk Evaluation and Mitigation Strategy (REMS) and Element to Assure Safe Use (ETASU) status for mifepristone, the drug regime that can medically induce abortion and help provide miscarriage treatment.

The AAFP seeks changes in the drug's current REMS designation to conform to current evidence. This aligns with other medical specialty organizations, such as the American College of Obstetricians and Gynecologists. Recent research also indicates the agency's safety protocols are particularly stringent for the drug. Most importantly, the current drug label creates an unnecessary health care barrier for women who need it the most.

Section 501-1 of the *Food, Drugs, and Cosmetics Act* (21 U.S.C. 355-1) indicates that the agency must evaluate if a drug's risks outweigh benefits. Since mifepristone entered the market in 2000, nearly 3 million women have used it, along with misoprostol, for essential medical care with a high degree of effectiveness (over 97%) and minor complication risks (less than 1%), particularly when accessing it early. In addition, the drug regime poses far fewer risks than medications with similar safety standards in place such as Accutane, which is associated with risk for birth defects. For women, particularly those in rural and medically-underserved areas who typically lack health care options, current protocols may result in delays that may increase their need for surgical abortion. This also applies for those who may need miscarriage treatment where efficient mifepristone usage may be the most patient-centered option.

Again, we urge your consideration of this request. For more information, please contact Sonya Clay, Government Relations Representative, at 202-232-9033 or [sclay@aafp.org](mailto:sclay@aafp.org).

Sincerely,

Michael L. Munger, MD, FFAFP  
Board Chair

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